

Expert Report of Donald L. Zink, Ph.D.

Prepared for: Robert E. McDivitt, III, Esq. McDonnell & Associates, P.C. 500 Marlton Pike W Cherry Hill, NJ 08002

Prepared by: Donald L. Zink, Ph.D. IEH Laboratories and Consulting Group 15300 Bothell Way NE Lake Forest Park, WA 98155

February 20, 2019

INTRODUCTION

Qualifications

I am President of the Division of Foods & Regulatory Compliance at IEH Laboratories and Consulting Group, where I have been employed since November 2015.

I hold a B.S. in Biology from Abilene Christian University (1974); M.S. in Microbiology from Texas A&M University (1976) and a Ph.D. in Biochemistry and Biophysics from Texas A&M University (1978).

My consulting practice involves providing technical services to help my clients detect, prevent and manage foodborne hazards and associated health risks. I am frequently retained to assess products that have the potential, or were shown, to contain foodborne hazards or other adulterants. Such consulting often involves advising on responses to product recalls or illness outbreaks and in the disposition of affected food products.

Prior to my employment by IEH Laboratories and Consulting group, I held several positions with the U.S. Food and Drug Administration (FDA) and with several different companies in the food industry. During my career, I conducted research on the nature of foodborne hazards and controlling foodborne hazards. I have received education and specialized training and I have over 40 years of experience in food safety.

I held positions at the FDA from 2002 to 2015 in the Center for Food Safety and Applied Nutrition (CFSAN). My positions included serving as Senior Food Scientist in the Office of Food Safety (2002 – 2009) and Senior Science Advisor in the Office of the Center Director. As a Senior Food Scientist, I provided scientific support on food adulteration issues primarily related to microbiological hazards and on food processing technology related to plant and dairy foods, beverages and infant formula. I served as the Center's expert, principal advisor and spokesperson in matters of regulatory science and research. I also served as the Center's principal subject matter expert on food microbiology and food processing and I advised FDA's Office of Regulatory Affairs, Office of Chief Counsel and the U.S. Department of Justice on food adulteration, the significance of foodborne hazards, field investigation strategy and scientific and technical issues related to the agency's enforcement and prosecution activities.

Prior to the FDA, I held positions with three different food companies. Initially, I served as a Manager of Food Science and Technology at Campbell Soup Company (1983 – 1990). At Campbell Soup, I became familiar with a variety of different food processes including canning, frozen food manufacturing, fresh produce processing, baking, poultry processing, and juice beverages. Following my time at Campbell Soup Company, I went on to hold several positions with the Carnation Company (a Nestlé Company) and Nestlé USA, Inc. My

positions with Carnation and Nestlé included being a Manager of Quality Assurance for Carnation's Refrigerated Foods Division (1990 to 1991) and ultimately as Director of Food Safety for Nestlé USA, Inc. (1991 to 2000). After my time with Nestlé, I served as Vice President of Research and Development and Product Safety for Future Beef, LLC (2000 to 2002), a producer of raw and processed beef products

Prior to my time in the food industry, I held Assistant Professor positions at the College of Veterinary Medicine at Texas A&M University (1978 to 1980) and in the Department of Microbiology & Immunology and Department of food Science at the University of Arizona (1980 to 1983)

I have authored over 40 scientific publications on various food safety issues and the control of foodborne hazards. Additionally, I have received special invitations globally and have given numerous lectures and presentations on foodborne hazards, risk assessment, food safety policy and food regulation.

I became a Certified Food Scientist in 2013, I served as a member of the executive board of the International Association for Food Protection (IAFP) from 2011 to 2016, and as President of IAFP in 2015. I have received numerous awards during my service with the FDA including the FDA Award of Merit (2010) and the FDA Distinguished Career Service Award (2015). A current copy of my *curriculum vitae* is attached as appendix A.

SCOPE OF WORK AND EXPERT OPINIONS

- 1. I was retained by Robert E. McDivitt, III, Esq. of McDonnell & Associates, P.C and asked to read and evaluate documents related to litigation involving Noujoud Achkar, Joseph Achkar, Wisconsin Cheese Group, LLC and Walmart, Inc. (United States District Court, Eastern District of Pennsylvania, No. 5:18-cv-2860). A list of the documents I have reviewed is provided in Appendix B.
- 2. Based on my knowledge, skill, education, training and experience, I am qualified to render an expert opinion in this matter. My opinions flow from conclusions reached from reading the above referenced materials as well as my professional knowledge, experience, education, skills and training.
- 3. On May 1, 2017, Noujoud Achkar purchased a La Morenita Brand queso fresco cheese product with a sell-by date of 04/18/17 from the dairy case of a Walmart store between the hours of approximately 5:00 and 7:00 PM. The cheese was cold to the touch when purchased and was immediately taken home for consumption within less than one-half hour.
- 4. Noujoud Achkar opened the sealed package with a clean knife, sliced the cheese and consumed a single piece of cheese with Pita bread.

- 5. Within one hour of consuming the cheese, La Morenita Brand Queso Fresco cheese, she fell down. She was transported to the hospital emergency room by ambulance that same evening. She was diagnosed with listeriosis on May 3, 2017.
- 6. The Pennsylvania Department of Health, Lehigh County, received a sample of the remaining opened package of queso fresco cheese from the Achkar family on May 8, 2017. On May 12, 2017, the Pennsylvania Department of Health, Bureau of laboratories completed an analysis of the cheese sample and reported finding *Listeria monocytogenes*.
- 7. Based on the facts and declarations presented to me, I am asked to believe that Mrs. Noujoud Achkar became ill within approximately 1 hour of consuming a single slice of unopened cheese taken from a previously sealed package of cheese. Based on my expert knowledge of the pathogenesis of *L. monocytogenes* and in consideration of Mrs. Achkar's age and immuno-compromised condition, it is simply impossible for *L. monocytogenes* to infect a host and replicate in the human body to the extent needed to cause symptomatic illness within one hour. Whatever the source of Mrs. Achkar's illness, it certainly was not the cheese she consumed less than one hour before exhibiting symptoms of illness.
- 8. In the 4 weeks prior to becoming ill, Noujoud Achkar reportedly consumed (in addition to the queso fresco cheese) string cheese (ate), whole milk (ate), butter (likely ate), fruit (beans, oranges, fresh red round tomatoes) (likely ate), deli sliced ham (ate), and iceberg lettuce (likely ate).
- 9. A blood specimen was collected from Noujoud Achkar on May 3, 2017 and this specimen tested positive for *Listeria monocytogenes* on that same day.
- 10. On May 26, 2017, the Pennsylvania health department reported that the clinical isolate from Mrs. Achkar was a PFGE match to the cheese sample isolate. Subsequently, on June 19, 2017, a total of three clinical isolates and the cheese isolate were reported to be highly related by whole genome sequencing. The clinical isolates included a patient from New Jersey, a patient from Texas and the isolate from Mrs. Achkar from Pennsylvania. The Texas and New Jersey patients reportedly did not consume La Morenita Brand Queso Fresco cheese.
- 11. In a May 19, 2017 email, a CDC epidemiologist communicated that the whole genome sequence of the *L. monocytogenes* isolate from PA (referring to Mrs. Achkar's blood isolate, I think) was a close match to a case of listeriosis in Maine and to four environmental swab isolates from Rhode Island.
- 12. On May 25, 2017, it was reported that New York state had 7 listeria isolates in the preceding two months that were a PFGE match to the isolate from Mrs. Achkar and the La Morenita Brand Queso Fresco Cheese.

- 13. On April 2, 2018, the CDC reopened the investigation due to the finding of three additional cases of illness (2 from Iowa and 1 from Indiana) where the clinical isolated matched those from Noujoud Achkar and the La Morenita Brand Queso Fresco cheese. These three new patients are of Middle Eastern ethnicity and all reported consuming Middle Eastern-style cheeses, including an Armenian-style string cheese. No common cheese consumption was found and none of the cheese samples tested positive for *L. monocytogenes*.
- 14. I believe that although the *L. monocytogenes* isolated from Mrs. Achkar's blood sample and the opened package of queso fresco cheese were highly related by PFGE typing and whole genome sequencing, we cannot conclude that the cheese was the source of the strain that caused Mrs. Achkar's illness. It is far more likely that the opened package of cheese became contaminated with the matching strain of *L. monocytogenes* from the refrigerator itself or from other foods in the refrigerator that were not available for testing by the Pennsylvania Department of Health.
- 15. Modern food packaging is designed to hermetically seal the food in the package and prevent contamination. There is no evidence that the package of cheese purchased by Mrs. Achkar on May 1, 2017 had any defect in its packaging or that that it was leaking. The packaging material for this cheese would have prevented the cheese from becoming contaminated from the environment during warehousing, distribution, retail sale, and storage by the consumer. Walmart distribution centers, trucks and the retail store could not have been a source of contamination of the cheese. Contamination of the cheese could only have occurred during or after the package was cut open.
- 16. The FDA and various state health departments discovered numerous clinical and environmental strains of *L. monocytogenes* that were highly related to the isolates from Mrs. Achkar's blood sample and from the open package of queso fresco cheese. Despite the best efforts of these agencies, they were unable to establish any link between cases of illness and a specific food. It is interesting to note that several of these patients were of Middle Eastern culture and consumed similar cheese products, particularly a Middle Eastern-style string cheese. Persons who have suffered serious foodborne illness often have difficultly remembering the foods they have consumed in the past week or month and this fact often confounds epidemiological investigations.
- 17. FDA inspections of Wisconsin Cheese's facility on April 26, 2016 and June 28, 2017, included collection of environmental samples (83 swabs collected on April 26, 2016 and 105 swabs collected on June 28, 2017). None of these swabs tested by FDA yielded *L. monocytogenes*. Neither of these inspections found any major objectionable conditions and no FDA-483 was issued.
- 18. FDA reported that "Wisconsin Cheese Group has been testing every vat of cheese produced at 1722 12th Street for *Listeria monocytogenes* for 15+ years and have never received a positive result for *Lm*." (FDA Records 12-4-18 (52 pages).pdf, page 6).

- 19. In its summary of the FDA inspection of June 28, 2017, the Wisconsin Cheese Group facility in Monroe, WI reported that they learned from the FDA investigators ". . .that another cheese (not produced by Wisconsin Cheese Group), tested positive for *Lm* with the same genetic sequence. This cheese was located in a consumer's refrigerator who complained of illness." (FDA Records 12-4-18 (52 pages), page 8).
- 20. All available information suggests that the Wisconsin Cheese Group facility in Monroe, WI was operated in an exemplary manner as evidenced by the results of comprehensive FDA inspections of this facility both before the date on which the implicated queso fresco cheese was manufactured and after the date of manufacture. In both of these FDA inspections, agency investigators took substantial numbers of environmental swabs and failed to find any evidence of *L. monocytogenes*. It would be interesting to learn more from the FDA about the cheese produced by another manufacturer that tested positive for *L. monocytogenes* with the same genetic sequence as that from Mr. Achkar's blood sample. This cheese could very well be the source of the numerous clinical cases with matching DNA sequences.

SIGNATURE PAGE

Respectfully submitted,

Donald L. Zink, Ph.D.

President – Division of Foods and Regulatory Compliance IEH Laboratories and Consulting Group

Appendix A – Curriculum Vitae of Donald Zink, Ph.D.

PROFESSIONAL EXPERIENCE

IEH LABORATORIES AND CONSULTING GROUP, LAKE FORREST, WA

President – Division of Foods & Regulatory Compliance

2015 - present

Leads the food safety and food processing consulting group of IEH Laboratories and Consulting Group. Areas of particular expertise in the microbiological and chemical safety of processed foods and fresh produce and in-depth experience are low acid canned food thermal processing, aseptic processing, ice cream production, chocolate and confectionary products, infant formula production, beverage production (coffee, tea and juices and wine), fermented and acidified foods, frozen food production, refrigerated food production and baked goods production.

U.S. FOOD AND DRUG ADMINISTRATION, COLLEGE PARK, MD

Senior Science Advisor, CFSAN

2009 - 2015

Served as the Chief Scientist for the U.S. Food & Drug Administration's Center for Food Safety and Applied Nutrition, and as advisor to the Center Director on the significance of new and ongoing scientific developments that affected the Center's research programs and policies. Provided advice, consultation, and management oversight to appropriate representatives associated with partnerships with academia and other consortia. Fostered partnerships and effective communication with academia, private industry, trade associations, public sector groups, governmental agencies, commodity groups, and professional organizations. Served as the Center's principal subject matter expert on food microbiology and food processing and interacted with the Center's Office of Compliance to review and support center enforcement actions. Served as a subject matter expert for FDA's Office of Regulatory Affairs and supported field investigations conducted by the agency and held investigators credentials. Worked with center stakeholders to develop a research strategy that was aligned with Center priorities, maintained the center's research strategic plan and recommended and authorized new research initiatives. Provided leadership for the development of short-, medium-, and long-term strategic research program plans. Coordinated CFSAN scientific research with other federal agencies including USDA, NIH, EPA and DARPA.

Provided authoritative advice, assistance, and recommendations to the Center Director on scientific disputes and served as the Center's designated official on issues regarding the resolution of scientific disputes.

Represented CFSAN to the Agency's Senior Science Council and to the Office of Food and Veterinary Medicine's Science and Research Steering Committee. Represented the Center to FDA's Office of the Chief Scientist.

Served as the Center's expert, principal advisor and spokesperson for science, research and data needs in communications with top Agency officials, and officials throughout the Federal government and the scientific and research communities.

Senior Food Scientist 2002 – 2009

Senior Food Scientist with the U.S. Food & Drug Administration, Center for Food Safety and Applied Nutrition, Office of Plant and Dairy Foods and Beverages. Lead Scientist for food processing and food microbiological issues related to plant and dairy foods, beverages and infant formula.

Future Beef Operations, LLC, Parker, CO

Vice-President – R & D and Product Safety

2000 - 2002

Responsible for leading research and development activities that add customer and consumer value to a complete line of fresh beef products. Also, responsible for leading a team of food safety and meat science professionals to develop strategies and implement processes that ensure the safety of fresh beef products produced by Future Beef operations.

Nestlé USA, Inc., Glendale, CA

Director – Food Safety

1991-2000

Responsible for developing and implementing policies that ensured the safety of foods produced by Nestlè USA, its licensees and co-packers. At the time, Nestlé USA was a company with \$8.0 billion in annual food sales and operated more than 40 manufacturing plants in the U.S. and had more than 120 licensees and co-manufacturers. Responsible for polices that ensured the safety of products manufactured by Nestlé USA and its co-manufacturers. Represented Nestlé USA to food safety and quality leadership of Nestlé, SA in Vevey, Switzerland.

Carnation Company, Glendale, CA (a Nestlé Company)

Manager – Quality Assurance

1990 – 1991

Responsible for division quality assurance functions for Carnation Refrigerated Foods Division, a \$150 million producer of refrigerated pasta and sauces. The division operated a single plant in Danville, VA.

Campbell Soup Company, Camden, NJ

Manager – Food Science & Technology

1983-1990

Responsible for planning and direction of food safety and microbiology research programs related to product safety and shelf - life. Provided guidance and research support to product development and marketing groups in the development of new products and processes. These responsibilities included all product lines of Campbell Soup Company. At the time, Campbell Soup Company produced both fresh and processed foods with annual sales of \$6.5 billion.

The University of Arizona, Tucson, AZ

Assistant Professor 1980 – 1983

Jointly appointed in the College of Science, Department of Microbiology & Immunology and the College of Agriculture, Department of Nutrition and Food Science. My research program was directed to genetic basis of bacterial virulence and food safety. Continued work begun at Texas A&M University into the genetic basis of virulence for *Yersinia enterocolitica*. This research program led to the development of several simple tests for the virulence of this species. We were able to clone the virulence genes from the *Yersinia* plasmid into *E. coli*. Taught upper level courses in bacterial genetics and pathogenic microbiology.

Texas A&M University, College Station, TX

Assistant Professor 1978 – 1980

Appointed in the College of Veterinary Medicine, Department of Veterinary Microbiology and Parasitology. Research program was directed to the genetic and physiological basis of virulence of *Brucella* sp. and the development of diagnostic tests for veterinary pathogens. Purified the exotoxin of *Corynebacterium* pseudotuberculosis and showed that it was a potent hemolytic toxin. This toxin later became the basis of a diagnostic test for infection in sheep and goats. I continued the work with *Yersinia* that was begun during my graduate studies and at the Centers for Disease Control. Taught graduate and professional level courses in diagnostic microbiology and pathogenic microbiology.

Centers for Disease Control, Atlanta, GA

Visiting Scientist 1977

As I neared the end of my graduate studies, I received a grant from the National Foundation for Infectious Diseases to study the virulence of *Yersinia enterocolitica*, the subject of my graduate research. The Centers for Disease Control had recently investigated an outbreak of yersiniosis in upper New York State. I collaborated with other investigators at the CDC and was able to prove that genes on a plasmid determined the virulence of this organism. This work was published in <u>Nature</u>. Subsequent studies showed that all species of *Yersinia* owed their virulence to this plasmid. This finding explained the long-sought genetic basis for variability in the virulence of *Yersinia pestis*, the cause of bubonic plague.

EDUCATION

Abilene Christian University - B.S. - Biology 1974

Texas A&M University - M.S. - Microbiology 1976

Texas A&M University - Ph.D - Biochemistry & Biophysics 1978

SPECIAL ACTIVITIES and ACCREDITATIONS

Dr. Zink serves on various advisory boards for food and dietary supplement companies.

Past President, International Association for Food Protection, 2015 – 2016.

President, International Association for Food Protection, 2014 – 2015.

President-elect, International Association for Food Protection, 2013 – 2014.

Vice President, International Association for Food Protection, 2012 – 2013.

Secretary, International Association for Food Protection, 2011 – 2012.

Member and Sub-Committee Chairman, National Advisory Committee on Microbiological Criteria for Foods, 2003 – 2011.

Vice-Chairman, Committee on Food Microbiology, International Life Sciences Institute,

Washington, D.C. 1999 - 2002

Vice-Chairman, Committee on Program and Technical Review of the U.S. Army Natick Research,

Development and Engineering Center, National Academy of Sciences, National Research

Council, Commission on Engineering and Technical Systems, 1994-1997.

Member, Advisory Board, Center for Food Safety, College of Agriculture, Texas A&M University, College Station, TX 1997-1999

Chairman, Microbiological Safety and Control Working Group, Grocery Manufacturer's of America, Washington, D.C. 1996 – 2000

Member, Human Systems Panel - Laboratory Infrastructure Capabilities Study of the Institute for Defense Analysis. Study conducted for Department of Defense, 1994.

Lead Judge, Jr. Division, Biochemistry Section, California State Science Fair, 1995 – 2000

Certified Food Scientist – 2013 to 2018, renewable

Certified HACCP Instructor – International HACCP Alliance

Foundation Lecturer, American Society for Microbiology, 1984-85

PUBLICATIONS

- 1. Hanna, M.O., D.L. Zink, Z.L. Carpenter and C. Vanderzant. 1976. *Yersinia enterocolitica*-like organisms from vacuum-packaged beef and lamb. J. Food Sci. <u>41</u>: 1254-1256.
- 2. Hanna, M.O., J.C. Stewart, D.L. Zink, Z.L. Carpenter and C. Vanderzant. 1977. Development of *Yersinia enterocolitica* on raw and cooked beef and pork at different temperatures. J. Food Sci. 42: 1180-1184.
- 3. Zink, D.L., J.C. Feeley, J.G. Wells, J.C. Vickery, G.A. O'Donovan, and C. Vanderzant. 1978. Possible plasmid-mediated virulence in *Yersinia enterocolitica*. Trans. Gulf Coast Mol. Biol. Conf., Texas J. Sci. <u>4</u>: 155-163.
- 4. Hanna, M.O., J.C. Stewart, Z.L. Carpenter, D.L. Zink, and C. Vanderzant. 1979. Isolation and characteristics of *Yersinia enterocolitica* from meats. Contr. Microbiol. Immunol. <u>5</u>: 234-242.
- 5. Zink, D.L., J.C. Feeley, J.G. Wells, J.C. Vickery, W.R. Roof, C. Vanderzant and G.A. O'Donovan. 1980. Plasmid-mediated tissue-invasiveness in *Yersinia enterocolitica*. Nature 283: 224-226.
- 6. Heck, F.C., J.D. Williams, J. Pruett, R. Sanders, and D.L. Zink. 1980. Enzyme-linked immunosorbent assay for detecting antibodies to *Brucella abortus* in bovine milk and serum. Am. J. Vet. Res. <u>41</u>: 2082-2084.

- 7. Twedt, R.M., D.F. Brown, and D.L. Zink. 1981. Comparison of plasmid deoxyribonucleic acid contents, culture characteristics and indices of pathogenicity among selected strains of *Vibrio parahaemolyticus*. Infect. Immun. <u>33</u>(1): 322-325.
- 8. Heck, F.C., Williams, J.D., Zink, D.L., Gilmore, W.C., and Adams, L.G. 1981. Serologic profile for a cow experimentally infected with Brucella abortus. <u>British Veterinary Journal</u> 137(5):520-6.
- 9. Foltermann, K.F., J.R. Wild, D.L. Zink and G.A. O'Donovan. 1981. Regulatory variance of aspartate transcarbamylase among strains of Yersinia enterocolitica and *Yersinia enterocolitica*-like organisms. Current Microbiol. 6: 43-47.
- 10. Dubel, J.R., D.L. Zink, L.M. Kelley, S.A. Naqi and H.W. Renshaw. 1982. Bacterial antibiotic resistance: incidence of gentamicin resistant strains of *Escherichia coli* in the fecal microflora of commercial turkeys. Am. J. Vet. Res. <u>43</u>: 1786-1789.
- 11. Zink, D.L., R.V. Lachica and J.R. Dubel. 1982. *Yersinia enterocolitica* and *Yersinia enterocolitica*-like species: their pathogenicity and significance in foods. J. Food Safety 4(4): 223-241. DOI:10.1111/j.1745-4565.1982.tb00447.x
- 12. Lachica, R.V. and D.L. Zink. 1984. Determination of plasmid-associated hydrophobicity of *Yersinia enterocolitica* by a latex particle agglutination test. J. Clin. Microbiol. <u>19</u>(5):660-663.
- 13. Lachica, R.V and D.L. Zink. 1984. Plasmid-associated cell surface charge and hydrophobicity of *Yersinia enterocolitica*. Infect. Immun. 44(2): 540-543.
- 14. Lachica, R.V., D.L. Zink and W.R. Ferris. 1984. Association of fibril structure formation with cell surface properties of *Yersinia enterocolitica*. Infect. Immun. 46(1): 272-275.
- 15. Hsu, T.-S., H.W. Renshaw, C.W. Livingston, Jr., J.L. Augustine, D.L. Zink and B.B. Gauer. 1985. *Corynebacterium pseudotuberculosis* exotoxin: fatal hemolytic anemia induced in gnotobiotic neonatal small ruminants by parenteral administration of preparations containing exotoxin. Am. J. Vet. Res. 46: 1206-1211.
- 16. Refrigerated Foods and Microbiological Criteria Committee of the National Food Processors Association. 1988. Safety considerations for new generation refrigerated foods. Dairy and Food Sanitation 8: 5-7.
- 17. Refrigerated Foods and Microbiological Criteria Committee of the National Food Processors Association. 1988. Factors to be considered in establishing good manufacturing practices for the production of refrigerated foods. Dairy and Food Sanitation 8: 288-291.

- 18. Microbiology and Food Safety Committee of the National Food Processors Association. 1991. Good Laboratory Practices Food Microbiology Laboratories. Dairy, Food and Environmental Sanitation 11: 716-720.
- 19. Elliott, P. H., Evancho, G. M. and D. L. Zink. 1992. Microbiological evaluation of low-acid aseptic fillers. Food Technology 46(5): 116 & 118-122.
- 20. Microbiology and Food Safety Committee of the National Food Processors Association. 1993. Implementation of HACCP in A Food Processing Plant. Journal of Food Protection. 56(6): 548-554.
- 21. National Research Council. 1996. World-Class Research and Development. Characteristics for an Army Research, Development and Engineering Organization. National Academy Press, Washington, D.C.
- 22. National Research Council. 1997. Assessment of the U.S. Army Natick Research, Development and Engineering Center. National Academy Press, Washington, D.C.
- 23. Zink, Don L. 1997. The Impact of Consumer Demands and Trends on Food Processing. Emerg. Infect. Dis. 3(4): 467-469.
- 24. Zink, Don L. 2004. Agroterrorism: Issues of Reality. J. Food Science [Concise Reviews in Food Science] 69(2): 47.
- 25. National Advisory Committee on Microbiological Criteria for Foods. 2005. Considerations for Establishing Safety-Based Consume-By Date Labels for Refrigerated Ready-to-Eat Foods. J. Food Protect. 68(8):1761-1775. Note: Dr. Zink served as Chairman of the subcommittee that authored the report.
- 26. Sertkaya, A., Berlind, A., Lange, R. and Zink, D.L. 2006. Top Ten Food Safety Problems in the United States Food Processing Industry. Food Protection Trends. 26(5):310-315.
- 27. Sheth, A.N., Wiersma, P., Atrubin, D., Dubey, V., Zink, D., Skinner, G., Doerr, F., Juliao, P., Gonzales, G., Burnett, C., Drenzek, C., Shuler, C., Austin, J., Ellis, A., Maslanka, S., Sobel, J. International Outbreak of Botulism with Prolonged Toxemia Caused by Commercial Carrot Juice. 2008. Clin. Infect. Dis. 47(10): 1245-1251.
- 28. National Advisory Committee on Microbiological Criteria for Foods. 2010. Parameters for Determining Inoculated Pack/Challenge Study Protocols. J. Food Protect. <u>73(1)</u>: 140-202. Note: Dr. Zink served as Chairman of the sub-committee that authored the report.
- 29. Sachdeva, A., Defibaugh-Chavez, S.L.H., Day, J.B., Zink, D., Sharma, S.K. 2010. Detection and confirmation of *Clostridium botulinum* in Water Used for Cooling at a Plant Producing

- Low-Acid Canned Foods. Appl. Environ. Micro. <u>76</u>(22): 7653-7657. DOI: 10.1128/AEM.00820-10.
- 30. Sheth, A.N., Hoekstra, M., Patel, N., Ewald, G., Lord, C., Clarke, C. Villamil, E., Niksich, K., Bopp, C., Nguyen, T., Zink, D., Lynch, M. 2011. A national outbreak of Salmonella Tennessee infections from contaminated peanut butter: a new food vehicle for salmonellosis in the United States. Clin. Infect. Dis. 53(4):356-362.
- 31. Karen P. Neil, Gwen Biggerstaff, J. Kathryn MacDonald, Eija Trees, Carlota Medus, Kimberlee A. Musser, Steven G. Stroika, Don Zink, and Mark J. Sotir. 2012. A Novel Vehicle for Transmission of *Escherichia coli* O157:H7 to Humans: Multistate Outbreak of *E. coli* O157:H7 Infections Associated With Consumption of Ready-to-Bake Commercial Prepackaged Cookie Dough—United States, 2009. Clin Infect Dis. (2012) 54(4): 511-518.
- 32. Patricia C. Juliao, Susan Maslanka, Janet Dykes, Linda Gaul, Satish Bagdure, Lynae Granzow-Kibiger, Ellen Salehi, Donald Zink, Robert P. Neligan, Casey Barton-Behravesh, CarolineLúquez, Matthew Biggerstaff, Michael Lynch, Christine Olson, Ian Williams, Ezra J. Barzilay. 2013. A National Outbreak of Foodborne Botulism Associated with a Widely Distributed Commercial Canned Hot Dog Chili Sauce. Clin. Infect. Dis. (2013) 56(3): 376–382.
- 33. <u>Birbari W, Bunning VK, Dessai U, Dole R, Engeljohn D, Garrett S, Glass K, Golden D, Grooters SV, Hardin M, Hoover D, Johnson L, Knabel S, Natrajan N, Ruple A, Tauxe R, Whitaker R, Zink D. 2013. Expedited response to the questions posed by the United States Department of Agriculture agricultural marketing service to support ground beef purchase for the federal food and nutrition assistance programs. <u>J Food Prot.</u> 76(3):523-37. DOI:10.4315/0362-028X.JFP-12-453.</u>
- 34. Uma Basavanna, Narjol González-Escalona, Ruth Timme, Shomik Datta, Brianna Schoen, Eric Brown, Donald Zink, and Shashi Sharma. 2013. Draft Genome Sequence of a *Clostridium botulinum* Isolate from Water Used for Cooling at a Plant Producing Low-Acid Canned Foods. Genome Announc. 2013 Jan-Feb; 1(1): e00200-12. DOI: 10.1128/genomeA.00200-12
- 35. Gonzalez-Escalona, N., Timme, R., Raphael, B.H., Zink, D., and Sharma, S.K. 2014. Whole genome Single-Nucleotide-Polymorphism Analysis for Discrimination of *Clostridium botulinum* Group I Strains. Appl. Environ. Microbiol. 80(7): 2125-2132. DOI:10.1128/AEM.03934-13.
- 36. Gonzalez-Escalona, N, Thirunavukkarasu, N., Singh, A., Toro, M., Brown, E.W., Zink, D., Rummel, A. and Sharma, S.K. 2014. Draft Genome Sequence of Bivalent Clostridium botulinum Strain IBCA10-7060, Encoding Botulinum Neurotoxin B and a New FA Mosaic Type. Genome Announcements 12/2014; 2(6):e01275-14. DOI: 10.1128/genomeA.01275-14.

- 37. Viazis, S., Beal, J.K., Monahan, C., Lanier, W.A., Kreil, K.R., Melka, D.C., Boden, W.D., Dion, J.L., Miller, Z.A., Nguyen, T.A., Gieraltowski, L.B. and Zink. 2015. Laboratory, Environmental, and Epidemiologic Investigation and Regulatory Enforcement Actions in Response to an Outbreak of *Salmonella* Bredeney Infections Linked to Peanut Butter. Open Forum Infectious Diseases, 2015 2(3). DOI: 10.1093/ofid/ofv114
- 38. Chen, Y., Burall, L., Macarisin, D., Pouillot, R., Strain, E., De Jesus, A., Laasri, A., Wang, H., Ali, L., Tatavarthy, A., Zhang, G., Hu, L., Day, J., Kang, J., Sahu, S., Srinivasas, D., Klontz, K., Parish, M., Evans, P., Brown, E., Hammack, T., Zink, D., Datta, A. 2016. Prevalence and Level of Listeria monocytogenes in Ice Cream Linked to a Listeriosis Outbreak in the United States. J. Food Protect. 79(11):1828-1832. http://dx.doi.org/DOI:10.4315/0362-028X.JFP-16-208
- 39. Sahu, Surasshi N., Kim, Bupmo, Ferguson, Martine S., Zink, Don L., Datta, Atin R. 2016. Growth Potential of *Listeria monocytogenes* in artificially contaminated celery and chicken salad. Food Control. (in press) http://dx.doi.org/10.1016/j.foodcont.2016.10.044
- 40. Chen, Y., Pouillot, R., Burall, L., Strain, E., VanDoren, J. M., DeJesus, A.J., A., Laasri, Wang, H., Ali, L., Tatavarthy, A., Zhang, G., Hu, L., Day, J., Sheth, I., Ta., Kang, J., Sahu, S., Srinivasas, D., Brown, E., Parish, M., Zink, D., Datta, A., Hammack, T. Macarisin, D. 2017. Comparative Evaluation of direct plating and most probable number for enumeration of low levels of *Listeria* monocytogenes in naturally contaminated ice cream products. Int. J. Food Microbiol. 241:15-22. http://dx.doi.org/10.1016/j.ifoodmicro.2016.09.021
- 41. Praseeda Mullasseril¹, Nagarajan Thirunavukkarasu¹, Gowri Manickam¹, Ajay Singh², Christine Pillai¹, Larry Stanker³, David Hodge⁴, Donald Zink⁵, Eric Brown¹, Thomas Hammack¹, and Shashi Sharma^{1.} 2017. Immuno-PCR Assay for the Detection of Type A, B, E, and F Botulinum Neurotoxins in Food Matrices. (manuscript submitted to Applied and Environmental Microbiology)

PRESENTATIONS (Partial Listing)

- 1. 103rd Annual Meeting of the American Society for Microbiology. May 18 22, 2003. Emerging Foodborne Pathogen Enterobacter sakazakii. (Symposium)
- 2. 12th World Congress of Food Science and Technology. July 19, 2003. Chicago, IL. Food Security in a Global Economy (Roundtable Session).
- 3. Ivan Parkin Lecture. International Association for Food Protection. August 10, 2003. On the Trail of Food Safety From the Early Days to the Future.

- 4. 2003 Annual Meeting of the International Association for Food Protection. August 10 14, 2003. Process Control Strategies for Reducing Foodborne Listeriosis. In the Symposium Session "Use of Food Safety Objectives and Other Risk-based Approaches to reduce Foodborne Listeriosis. (Invited Speaker)
- John L. Etchell's Memorial Lecture, North Carolina State University. April 12, 2007.
 "Emerging Food Safety Issues: Recent Outbreaks and Food Safety Implications". (Invited Speaker)
- 6. 2007 Annual Meeting of Pickle Packers International. October 3, 2007. Memphis, TN. Emerging Food Safety Issues. (Invited Speaker).
- 7. McDonald's Sanitation and Food Safety Workshop. October 9 10, 2007. "What's New at FDA Priorities and Emerging Issues." Oak Brook, IL (Invited Speaker)
- 8. 2009 Annual Meeting of the International Association for Food Protection. July 12 15, 2009. Regulatory Implications of Persistence in the Processing Environment, the Product, and Primary Production. In the Symposium Session: "Pathogen and Spoilage Persistence in the Processing environment and Food Products: Where, Why and How Do We Know." (Invited Speaker)
- 9. 2009 FDA Southeast Region Annual Retail Food Safety Seminar. November 3 5, 2009. "Emerging Pathogens of Concern." Held at Myrtle Beach, SC. (Invited Speaker)
- Center for Produce Safety Produce Research Priorities Meeting. June 24, 2010.
 "CFSAN Fresh Produce Research Priorities." Held at UC Davis Mondavi Center, Davis, CA. (Invited speaker)
- 11. 2010 FDA Denver District Staff Conference. July 13 15, 2010. "Preventive Controls." Held at Colorado School of Mines, Golden, CO. (Invited speaker)
- 12. 3rd Annual Molecular Methods in Food Microbiology Symposium and Workshop Series. June 28, 2010. Molecular Epidemiology: It's Impact in the Fight to Control Salmonellosis. Held at Colorado State University. (Keynote Address).
- 13. 2010 Annual Meeting of the International Association for Food Protection. August 1 4, 2010. Environmental Sampling Sites Versus Food Contact Surfaces If, When and Where to Sample (Regulatory Perspective) in the Symposium Session: "Microbiological Environmental Testing and Validation: Leading-edge Issues for Low-moisture Foods." (Invited Speaker)
- 14. 2010 Annual Meeting of the International Association for Food Protection. August 1-4, 2010. FDA Perspectives on the Need for Multidisciplinary Approaches to Food Safety. In

- the Symposium Session: Human Pathogens Associated with Edible Plants (co-organizer of the symposium)
- 15. 2010 Annual Meeting of the International Association for Food Protection. August 1 4, 2010. New and Emerging Food Safety Regulations Related to Testing, Records Access and the Food Registry. In the Symposium Session: Food and Food Environment Test Considerations in View of Changing Regulations (invited symposium speaker)
- 16. 87th Annual Conference of the New York State Association for food Protection. September 22, 2010. "Impact of New Technologies on Food Safety." Held at the Doubletree Hotel in East Syracuse, NY. (Invited speaker)
- 17. 9th Annual York College FDA Food Safety Workshop. November 2, 2010. "Environmental Sampling – Why do it and what to expect." Held at York College, Jamaica, NY. (Invited speaker)
- 18. 114th Annual Meeting of the United States Animal Health Association. November 11 17, 2010. Minneapolis, MN. Assessment of Food as a Source of Exposure to *Mycobacterium avium* subspecies *paratuberculosis* (MAP). (Invited speaker)
- 19. 2011 International Life Science Institute Annual Meeting. January 24, 2011. "A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration: The Reportable Food Registry." Held at Lake Buena Vista, FL.
- 20. 2011 Personal Care Products Council Science Summit. April 13, 2011. "Science and the New Administration." Held at the Madison Hotel, Washington, DC. (Keynote Address)
- 21. 2011 Annual Meeting of the International Association for Food Protection. July 31 4, 2011. FDA Approach Risk Prioritization for Inspections, Microbiological Sampling and Egg Rule Implementation. (Invited speaker)
- 22. 2011 Annual Meeting of Central Atlantic Association for Food Protection, Rutgers University.
- 23. 2012 Joint Institute for Food Safety and Applied Nutrition. Advisory Council 2012 Spring Symposium. May 16, 2012. Turning the page from "chemo and microphobia" to "Food Safety" Microbiological Issues. (Invited speaker)
- 24. 2012 Annual Meeting of the International Association for Food Protection. July 22 25, 2012. *Salmonella* in Low-moisture Foods: Challenges and Potential Solutions. (Invited symposium speaker)

- 25. 2012 11th Annual Meeting of the Brazilian Association for Food Protection. "Foodborne Disease Outbreak Detection Today's Reality and the Promise of the Future." Held in Sao Palo, Brazil. (Invited speaker)
- 26. 2013 Annual Meeting of the International Association for Food Protection. July 28 31, 2013. Call to Action Let's Put Water on a HACCP Plan. (Invited roundtable speaker)
- 27. 2013 Annual Meeting of the International Association for Food Protection. July 28 31, 2013. What is Dry Cleaning vs. Dry Sanitation? What Defines a Dry Plant? (Invited symposium speaker)
- 28. 2014 Annual Meeting of the International Association for Food Protection. August 3 6, 2014. Food Safety Issues in India the U.S. FDA Perspective. (Invited symposium speaker)
- 29. 2014 Annual Meeting of the International Association for Food Protection. August 3 6, 2014. "Plant Construction Problems That Have Been Identified as Direct Factors in an Outbreak." (Invited symposium speaker)
- 30. 5th Annual Meeting of the Quebec Association for Food Protection. September 17 18, 2014. "Food Safety Strategy and Future Needs. Held in Levis, Quebec, Canada. (Invited speaker)
- 31. 2015 European Symposium on Food Safety. April 20 22, 2015. "Listeria monocytogenes: Recent U.S. Outbreaks and Implications for Control in No Growth Foods." Held in Cardiff, Wales, UK (Invited Speaker)
- 32. 2015 Department of Nutrition and Food Science Research Day. May 1, 2015. "Current Issues in food Safety and Nutrition: Science Struggling to be Heard". National Agricultural Library, Beltsville, MD (Keynote Speaker).
- 33. 2015 Annual Meeting of the New York State Association for Food Protection. September 22 23, 2015. "Listeria research at FDA-CFSAN." Syracuse, NY (invited speaker).
- 34. 2016 Arkansas Association for Food Protection Annual Conference. September 13 15, 2016. "The Changing Face of Food Safety." Fayetteville, AR (invited speaker).
- 35. 2016 Washington State Association for Food Protection Annual Conference. September 21 23, 2016. Hot Topics in Food Safety. Chelan, WA (invited speaker).

Appendix B

The following documents were provided in electronic form to Dr. Donald Zink for review and consideration in preparing this expert report:

- 1. Complaint.pdf
- 2. Deposition Transcript Achkar, Noujoud.pdf
- 3. FDA Records 12-4-18 (52 pages).pdf
- 4. P's Expert Report Michael Sulzinski 1-17-19.pdf
- 5. PA Dept of Health Records 11-5-18 (16 pages).pdf
- 6. PA Dept of Health Records 12-7-18 (124 pages).pdf
- 7. WM's Answers to P's Rogs 11-23-18.pdf
- 8. WM's Answers to Wisconsin Cheese's Rogs 11-23-18.pdf
- 9. WM's Response to P's RFPD 11-23-18.pdf
- 10. WM's Response to Wisconsin Cheese's RFPD 11-23-18.pdf
- 11. Zink encl records for review 2-8-19.pdf